K111303

SharpLight

DEC 2 1 2011

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92

Submitter Information

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Device Classification

Proprietary Device Name:	Dermatological Treatment Systems device family
Common name:	Multi-Application Dermatological Treatment device family
Product Code:	Primary GEX, Secondary NUV, ONG, ONE, ONF
Classification Name:	Laser Surgical Instrument, for use in General and Plastic Surgery and Dermatology
Classification Regulation:	21 CFR § 878.4810
Regulatory Class:	II

Identification of Legally Marketed Predicate Devices

SharpLight - BEAMAX/FORMAX Pulse Light device family -	K082876
Alma lasers - Harmony XL^{Tm} Multi-Application Platform -	K072564
Cutera Optional Pulsed Light Hand Piece Family -	K050047
Palomar LuxIR Fractional Hand piece -	K060069

Device Description

The Dermatologic Treatment Systems (DTS) device family and optional hand pieces, including Intensive Pulse Light (IPL) Infrared light (IR) and Laser light technologies for dermatological treatments by delivery of energy to the human skin. The device family is a modification to the BeaMax/ ForMax family (K082876), pulsed light energy device based on a filtered, Xenon flashlamp.

The DTS device family modification enhances capabilities of the legally cleared Beamax/ Formax device family by adding new hand pieces that are now supporting Laser and IR technologies as well as the IPL technology.

The Basic unit is a platform system, designed to support all treatment technologies hand pieces (i.e. IPL, IR and Laser).

The embedded software is the heart of the control system which provides a control of all of the parameters to the relevant hand piece, where the operator has the access to modify some parameters via the touch screen and every hand piece has its own operating screen.

Intended Use of Device

The DTS device family, a modification to the legally cleared device family (K082876), uses IPL, IR, Laser and RF energy sources, is intended for dermatological treatments.
The DTS device family is indicated for dermatological treatments such as, but not limited to:
* Hair removal in all skin types to the Fitzpatrick scale. Permanent Hair Reduction.
* Treatment of Vascular Lesions
* Treatment of Inflammatory Acne (acne vulgaris)
* Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae.
* Treatment of Wrinkles, rhytids and Periorbital Wrinkles
* Skin resurfacing (Acne scars)
* Treatment of Tattoos
* Treatment of Leg and Facial Vein Removal
* Treatment of photocoagulation of soft tissue in dermatologic applications
* Resurfacing of the skin, and for the treatment of facial wrinkles.

Safety & Effectiveness

The DTS device family was compared to the predicate devices in terms of intended use, indications for use, components, principles of operation, technological characteristics and safety features.
Based on the performance results provided (including test results and clinical data) and the analysis of similarities and differences presented above, SharpLight Technologies Ltd. believes that the proposed device family safe & effectiveness is substantially equivalent to the predicate devices without raising new safety and/or effectiveness issues.

Rational for Substantial Equivalency

Similarities:
The intended use and indications of the DTS device family are similar to the legally cleared predicate devices.
The technology, performance and most of the specifications of the DTS device family are similar to the legally marketed predicate devices
Differences:
The DTS device family wider indications for use enhances their capability to perform dermatological treatments, by using the different technologies (IPL, Laser and IR), while predicate devices are capable of supporting partial treatments only.

Substantial Equivalence Statement

Based on the above, it is SharpLight's opinion that the proposed DTS device family is substantially equivalent in terms design principles, performance features and of safety & effectiveness to the unmodified BeaMax/ ForMax family (K082876) legally cleared device and to the legally cleared predicate devices referred to in chapter 4 of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 1 2011

SharpLight Technologies, Ltd.
% Mr. Ilan Sharon
P.O. Box 4262
Zichron Yaacov
Israel 30900

Re: K111303
Trade/Device Name: Dermatological Treatment Device Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, GEI
Dated: December 16, 2011
Received: December 20, 2011

Dear Mr. Sharon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111303

Device Name: Dermatological Treatment Systems Device Family

Indications for Use:

The Dermatological Treatment Systems device family and optional Hand Piece family are intended for use in aesthetic and cosmetic applications and in selective treatments required in the medical specialties of dermatology.

The Dermatological Treatment device family and optional Hand pieces with 415 – 1200 nm wavelengths (with and without contact-cooling) are indicated for:

* Hair removal and Permanent Hair Reduction in all skin types (I-VI) to the Fitzpatrick scale - Recommended wavelengths in the range of 635-950 nm, 730-950 nm or 580-950 nm
* Treatment of Pigmented and Vascular Lesions in all skin types (I-VI) to the Fitzpatrick scale – Recommended wavelength in the range of 535-950 nm
* Treatment of Inflammatory Acne (acne vulgaris) in skin types (I-V) to the Fitzpatrick scale – Recommended wavelength in the range of 415-950 nm
* Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae in all skin types (I-VI) to the Fitzpatrick scale - Recommended wavelength in the range of 580-950 nm
* Treatment of Benign Pigmented Epidermal, Cutaneous and Vascular Lesions including warts; scars and striae in skin types (I-V) to the Fitzpatrick scale – Recommended wavelength in the range of 535-680 nm & 860-1200nm

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111303

Indications for Use

510(k) Number (if known): K111303

Device Name: Dermatological Treatment device family

Indications for Use: Continued from last page.

The Dermatological Treatment device family and optional Infrared (IR) Hand Pieces with 850 – 1750 nm wavelengths (with contact cooling) is indicated for:

* Dermatologic Treatment such as, but not limited to: photocoagulation of soft tissue (Scars, Wrinkles, Rhytids and Periorbital Wrinkles)

The Dermatological Treatment device family and optional Nd:YAG Laser 1064 nm Long Pulse (LP) Hand Pieces is indicated for:

* Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles.
* Removal or lightening of unwanted hair (with and without adjuvant preparation)
* Treatment of pseudofolliculitis barbae (PFB)

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K111303

Device Name: Dermatological Treatment device family

Indications for Use: Continued from last page.

The Dermatological Treatment device family and optional Nd:YAG Laser 1064 nm Long Pulse (LP) and Q-Switched Hand Pieces is indicated for:

* Benign vascular lesions such as, but not limited to treatment of: Port wine stains; Hemangiomas; Warts, Superficial and deep telangiectasias (venulectasias); Reticular veins (0.1-4.0 mm dia.) of the leg; Rosacea; Venus lake; Leg veins; Spider veins; Poikiloderma of Civatte; Angiomas
* Benign cutaneous lesions, such as, but not limited to: Warts; Scars; Striae; Psoriasis
* Benign pigmented lesions such as, but not limited to: Lentigos (age spots); Solar lentigos (sun spots); Cafe-au-lait macules; Seborrheic; keratoses; Nevi and nevus of Ota, Chloasma; Verrucae; Skin tags; Keratoses; The removal of black, blue or green tattoos (significant reduction in the intensity of black and /or blue/black tattoos); Plaques
* Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment and for patients with lesions that have not responded to other laser treatments.
* The non-ablative treatment of facial wrinkles, such as, but not limited to: Periocular wrinkles; Perioral wrinkles

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mam

(Division Sign-Off)
Division of Surgical, Orthopedic,
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510(k) Number K111303

Indications for Use

510(k) Number (if known): K111303

Device Name: Dermatological Treatment device family

Indications for Use: Continued from last page.

Continued : The Dermatological Treatment device family and optional Nd:YAG Laser 1064 nm Long Pulse (LP) and Q-Switched Hand Pieces is indicated for:

* Laser skin resurfacing procedures for the treatment of: Acne scars; Wrinkles
* Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
* Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The Dermatological Treatment device family and optional Nd:YAG Laser 532 nm Frequency Dabbler (FD) Long Pulse (LP) and Q-Switched Hand Pieces is indicated for:

* Tattoo removal: Light blue; Yellow; Red; Green
* Vascular lesions: Hemangiomas (Port wine stains/birthmarks, cavernous, cherry, spider); hemangiomas; Angiomas (cherry, spider); Telangiectasia; Spider nevi
* Benign pigmented lesions, such as, but not limited to: Cafe-au-lait (macules); Lentigines (senile and solar); Freckles (ephelides); Chloasma; Nevi; Nevus spillus, Nevus of Ota; Becker's Nevi;
* Other pigmented cutaneous lesions, such as, but not limited to: Verrucae; Skin tags; Keratoses; Plaques

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxn

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111303

Indications for Use

510(k) Number (if known): K111303

Device Name: Dermatological Treatment device family

Indications for Use: Continued from last page.

The Dermatological Treatment device family and optional Er:YAG Laser 2940 nm Long Pulse (LP) Hand Pieces, with standard and scanner accessory tips is indicated for:

Use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands) such as, but not limited to:

* Dermatology and plastic Surgery: Skin resurfacing; Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars);

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Prescription Use __X____
(Part 21 CFR 801 Subpart D)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Surgical, Orthopedic,
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510(k) Number K111303